

Metro Health

Conflict of Interest in Human Subject Research

Section	Clinical Research	Former Policy Number	None	Policy Number	CR (HRP) 21
Original Date	February 2011	Effective Date	June 2020	Next Review	June 2023

Δ Indicates Change

Policy Statement: Institutions involved or engaged in human subject research must ensure that the safety and welfare of study participants are protected and that the integrity of the research is never compromised as a result of financial interests or the pursuit of personal gain. Metro Health will consider all disclosures that meet the definition of a significant financial interest in human subjects’ research to be potentially problematic and therefore follow this policy as a means to review and manage these interests.

Key Words Conflict of Interest, Principal Investigator, Disclosure

Scope: This policy applies to any principal investigator and any other person (see “Covered Individual” below) who shares responsibility for the design, conduct or reporting of research at Metro Health.

- General:**
- A. This policy is not intended to suggest that every financial interest jeopardizes the welfare of the human subjects or the integrity of the research, but rather to ensure that the institution systematically reviews any financial interest that might result in an actual or perceived conflict of interest. In doing so, limit the conduct of human subjects’ research performed by financially interested individuals as appropriate to the degree of their disclosed interest.
 - B. Compensation in the form of a financial interest which may be affected by the outcome of the study shall be avoided. Examples of conflicts of interest due to compensation which require disclosure pursuant to this policy include, but are not limited to, consulting agreements, speaking or other fees, honoraria, gifts, licensing revenues, equity interests, loans or notes, including stock options, regardless of value, expectations of receiving equity interests, and/or other fees or compensation received from sponsors.
 - C. Covered individuals must disclose any potential conflicts of interest that exist or arise prior to approval of the research, during the conduct of the research and twelve months post study completion. These interests must be disclosed for all covered individuals on each initial application submitted to the Metro Health IRB. When a central IRB is being utilized, interests must be disclosed for all covered individuals on each *Central IRB - Transfer or New Form*. All new covered individuals, regardless of the IRB being utilized, are required to submit a *Conflict of Interest in Research Disclosure Form (CR HRP 21-A)* upon submission of a new study.
 - D. In addition, all covered individuals are required to submit an updated disclosure of significant financial interests at least annually by completing the Conflict of Interest in Research Disclosure Form (CR HRP 21-A) and, if applicable, by completing the Financial Interest Declaration of the Continuing Review Progress Report Form (CR HRP 34-A). If a covered individual discovers or acquires a new significant financial interest, they are required to notify the Metro Health Research Office within 30 days by submitting a revised Conflict of Interest in Research Disclosure Form (CR HRP 21-A).

Procedure

STEP	ACTION	RESPONSIBLE PARTY
1	Annual collection of financial disclosures from all individuals who are currently involved in human subjects research at Metro Health using the Conflict of Interest in Research Disclosure Form (CR HRP 21-A). The completed forms will be reviewed to determine if the reported information meets the definition of a significant financial interest.	Legal Services and Research Dept.

2	<p>Once a report meeting the definition of a significant financial interest has been identified, the Metro Health IRB will be notified and a meeting will be called with the following individuals:</p> <ul style="list-style-type: none"> • General Counsel, Metro Health • Compliance Officer, Metro Health • Metro Health IRB Member Representation • Institutional Official, Metro Health • Research Director, Metro Health 	<p>Research Dept.; Research Conflict of Interest Committee; Metro Health Institutional Review Board (IRB)</p>
3	<p>This group is responsible for reviewing and providing the Metro Health IRB with a documented recommendation 1) if the report constitutes a conflict of interest for the research being conducted at Metro Health, and 2) related actions to manage, reduce and/or eliminate the reported conflict. The recommendation will be based on the nature of the research question, the nature of the interest, how closely the interest is related to the research and the degree to which the interest may be affected by the research.</p> <p>The Metro Health IRB has the final authority to determine whether a conflict of interest has been eliminated or managed appropriately and will do so prior to approval of the research. The Metro Health IRB will provide interested individuals with the opportunity to discuss recommendations if they wish to do so.</p> <p><u>Possible management plans include, but are not limited to:</u></p> <p>Development of consent language to disclose the potential or actual conflict to the research subject;</p> <ul style="list-style-type: none"> • Requiring divestiture or termination of relevant economic interest; • In case of equity, imposing a bar on insider trading, or requiring the transfer of securities to an independent financial manager or blind trust, or limiting the timing of sales or distributions; • Requiring individual recusal from a study; • Altering participation of an individual in all, or a portion, of the research (e.g. cannot conduct data analysis, restricted from recruiting human subjects and/or conducting the informed consent process); • Independent monitoring of the research, (i.e. independent review of data and other retrospective review for bias, objectivity, comprehensiveness of reporting (versus withholding data) (e.g. independent data and safety monitoring board); • Independent monitoring of the consent process; • Requiring disclosure of the conflict to institutional committees, research participants, journals, and data safety monitoring boards. 	<p>Research Conflict of Interest Committee; Metro Health IRB</p>
4	<p>In the case where a central IRB is being utilized, the same reporting and process to eliminate or manage the covered individual's potential conflict of interest applies. The Metro Health IRB will communicate the interest and management plan to the central IRB via the covered individual with the expectation that the central IRB will follow the Metro Health recommendation and subsequent conditions for protocol approval. Implementation of the management plan will be verified with the central IRB when the Metro Health IRB receives notice of approval from the central IRB.</p>	<p>Investigator; Metro Health IRB</p>
5	<p>Based on funding sources, Metro Health may be required to report disclosures of individual financial conflicts of interest to appropriate regulatory authorities.</p>	<p>Institutional Official</p>

Definitions:

Conflict of Interest: Any situation in which financial or personal interest may compromise or appear to compromise an individual's professional judgment in designing, conducting or reporting research, **Δ** whether it is Domestic and/or Foreign/International.

Covered Individual: Any investigator (staff member, student, resident, fellow, trainee or administrator) or other individual (whether full-time, part-time, salaried or exempt) who shares responsibility for the design, conduct or reporting of research. This is inclusive of the immediate family members of this individual.

Financial Interest Related to the Research: Financial interest in the sponsor, product, or service being tested, or interest in the competitor of the sponsor or product or service being tested regardless of whether or not the value is readily ascertainable and **Δ** whether it is Domestic and/or Foreign/International

Human Subjects Research: All research meeting the definition of research performed with human subjects as defined in 45 CFR 46 and 21 CFR 56, regardless of the source of research funding or where the research is otherwise subject to federal regulation.

Immediate Family: An individual's spouse or domestic partner, dependent children and anyone else who resides with the individual or is the individual's dependent for tax purposes.

Significant Financial Interest in Research:

(1) A financial interest consisting of one or more of the following interests of the individual or individuals' immediate family that reasonably appears to be related to the individuals' research responsibilities:

- i. With regard to any **publicly** traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure which, when aggregated exceeds \$5,000. Remuneration includes, but is not limited to, salary or other payments for services not otherwise identified as salary (e.g. consulting fees, board member, paid authorship or honoraria); and equity interests (e.g. stocks, stock options or other ownership interest) as determined through reference to public prices or other reasonable measures of fair market value. **Δ**This includes all domestic and/or foreign affiliations (including foreign positions and scientific appointments, financial interest in foreign entities, research support from foreign entities, and any other foreign affiliations).
- ii. With regard to any **non-publicly** traded entity, **Δ** Domestic and/or Foreign/International, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the individual or individual's immediate family holds any equity interest (e.g. stock, stock option, or other ownership interest).
- iii. Intellectual property rights, **Δ** Domestic and/or Foreign/International, (e.g. patents, copyrights and royalties from such rights), upon receipt of income related to such rights and interests.

(2) Individuals must also disclose the occurrence of any reimbursed or sponsored travel, **Δ** Domestic and/or Foreign/International (i.e. that which is paid on behalf of the individual and not reimbursed to the individual so that the exact monetary value may not be readily available), related to their research responsibilities, provided however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources as provided in the regulations.

References 42 CFR, Part 50, Subpart F
45 CFR, Part 94
21 CFR 54.312
21 CFR 54.314
21 CFR 54. 320
21 CFR 54. 330
21 CFR 54. 601
21 CFR 54.807
21 CFR 54. 807
21 CFR 54. 814
21 CFR 54.860
<http://grants.nih.gov/grants/policy/coi/index.htm>

Related Metro Health Policy CR (HRP) 01 Metro Health Human Research Protection Program
CR (HRP) 02 Metro Health IRB – Authority and Purpose
CR (HRP) 06 Investigator Responsibilities
CR (HRP) 11 IRB Reciprocity and Authorization Agreements for Cooperative Research Activities
CR (HRP) 31 IRB Submission Requirements
CR (HRP) 34 Continuing Review Requirements
▲ CR (HRP) 150 Conflict of Interests of IRB Members

Input/Review Institutional Official
Metro Health Legal Services
Metro Health Department of Clinical Research

Issued By Department of Clinical Research

Approving Committee(s) NA Committee(s) NA Date

Director or VP Approval _____ **Type:** Ronald Grifka, MD FAAP, FACC, FSCAI,
Institutional Official, Metro Health

Attachments CR (HRP) 21-A: Conflict of Interest in Research Disclosure Form

Conflict of Interest - Research

Step 1. Read the policy.

Step 2. Answer the following questions in regard to any study being conducted at Metro Health in which you are the principal investigator or for which you share responsibility for the design, conduct, or reporting of research (you are identified as a sub-investigator or research personnel).

Yes No Do you or your immediate family (defined as spouse or domestic partner, dependent children, and anyone who resides with the individual dependent for tax purposes) have any of the following:

With regard to any **publicly** traded entity:

- Remuneration, domestic and/or foreign/international, (which includes salary and any payment for services not otherwise identified as salary) received from the entity in the twelve months preceding the disclosure and the value of any equity interest (which includes any stocks, stock options, or other ownership interest related to the research) in the entity as of the date of disclosure which, when aggregated (you and your immediate family combined), exceeds \$5,000 **and** no arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research.

With regard to any **non-publicly** traded entity:

- Remuneration, domestic and/or foreign/international, (which includes salary and any payment for services not otherwise identified as salary) received from the entity in the twelve months preceding the disclosure, which, when aggregated (you and your immediate family combined), exceeds \$5,000 or any equity interest (including any stocks, stock options, or other ownership interest related to the research) in the entity.

Yes No Are you or your immediate family, a paid or unpaid member of an advisory or executive board or do you or your immediate family have a paid or unpaid executive relationship, consulting agreement, or management responsibilities with a sponsoring company or providers of products or services being evaluated, whether domestic and/or foreign/international?

Yes No Do you or your immediate family receive gift funds, educational grants, subsidies or other remuneration from a sponsoring company, whether domestic and/or foreign/international?

Yes No Do you or your immediate family have any proprietary interest related to research including, but not limited to, a patent, trademark, copyright, or licensing agreement, whether domestic and/or foreign/international?

Yes No Have you gone on any trips that could be viewed as reimbursed or sponsored travel (i.e., that which is paid on your behalf and not reimbursed to you directly so that the exact monetary value may not be readily available), related to your research responsibilities, whether domestic and/or foreign/international?

If you answered "Yes" to any of the above questions please describe in detail the following:

- Entity or entities involved (name of company or entity in which the relationship exists);
- A detailed description of the relevant activities in which you are involved;
- Describe the amount of any payment received and/or the anticipated financial gain over the next 12 months.

Describe any other relationships, commitments, or activities that you or any members of your immediate family have that might present or reasonably appear to present a conflict of interest with your research. Also, please describe any steps planned to prevent the financial interest from interfering with the design, conduct, or reporting of the research, including interfering with the protection of participants.

Step 3. Certification

By submitting and signing this form, I certify that the above information is true and that I am in compliance with federal law, state law and all Metro Health policies related to conflicts of interest to the best of my knowledge. If I become aware that I have a conflict of interest during the conduct of any study and during the first year following the completion of the affected human research study, I will report the conflict to the Metro Health Research Dept. within 30 days.

Signature

Date

Printed Name